

Notice of Allowability

Application No.

09/865,579

Examiner

Juliet C. Switzer

Applicant(s)

TAYA ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to response 10/5/04; interviews 12/15/04 and 12/22/04.
2. ☒ The allowed claim(s) is/are 9, 10, 12 and 13.
3. ☒ The drawings filed on 29 May 2001 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>122204 and 121504.</u> |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Chris Raymond on 12/22/04.

In the interest of clarity, the following is a recitation of the status of all claims in this application. Claims 9, 10, 12, and 13 are pending and are allowed as written herein. Claim 9 is amended in this action. A detailed description of the amendments is included in the enclosed interview summary.

9. A method for detecting methicillin-resistant *Staphylococcus aureus* (MRSA) in a sample, said method comprising the steps of:

(a) preparing a reaction comprising:

a sample;

a first oligonucleotide primer comprising (i) a portion of the *mecA* gene of MRSA, wherein said portion is a target sequence and (ii) an RNA polymerase promoter sequence attached to the 5'-end of the sequence in (i);

a second oligonucleotide primer;

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an enzyme or a mixture of enzymes having (i) RNA-dependent DNA polymerase activity, (ii) ribonuclease activity that hydrolyzes RN of an RNA-DNA hybrid without hydrolyzing single-stranded and double-stranded RNA or DNA, (iii) DNA-dependent DNA polymerase activity, and (iv) DNA-dependent RNA polymerase activity; and

a cleaving oligonucleotide probe comprising a sequence complementary to a region overlapping with and adjacent to said target sequence;

(b) incubating said reaction mixture under conditions that allow the formation of a double-stranded cDNA product from said target sequence and the transcription of an RNA product from the double-stranded cDNA product; and

(c) detecting the RNA product transcribed from the double-stranded cDNA product,,

wherein:

(1) an oligonucleotide comprising at least 10 contiguous bases of the sequence recited in SEQ ID NO: 18 is used as the first primer, an oligonucleotide comprising at least 10 contiguous bases of the sequence recited in any of SEQ ID NO: 19, 20 or 21 is used as the second primer, and an oligonucleotide comprising the sequence recited in SEQ ID NO: 26 is used as the cleaving probe, or

(2) an oligonucleotide comprising at least 10 contiguous bases of the sequence recited in SEQ ID NO: 22 is used as the first primer, an oligonucleotide comprising at least 10 contiguous bases of the sequence recited in any of SEQ ID NO: 23 or 24 is used as the second primer, and an oligonucleotide comprising the sequence recited in SEQ ID NO: 27 is used as the cleaving probe, or

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(3) an oligonucleotide comprising at least 10 contiguous bases of the sequence recited in SEQ ID NO: 25 is used as the first primer, an oligonucleotide comprising at least 10 contiguous bases of the sequence recited in any of SEQ ID NO: 23 or 24 is used as the second primer, and an oligonucleotide comprising the sequence recited in SEQ ID NO: 28 is used as the cleaving probe.

10. The method of claim 9, wherein said RNA polymerase promoter sequence comprises the nucleotide sequence recited in SEQ ID NO: 30.

12. The method of claim 9, wherein the reaction mixture further comprises a detection probe comprising a sequence complementary to a portion of the RNA product transcribed from the double-stranded cDNA product, and wherein said detection probe is labeled with an intercalator fluorescent dye.

13. The method of claim 12, wherein said detection probe comprises SEQ ID NO: 20 or SEQ ID NO: 29.

2. The following is an examiner's statement of reasons for allowance: The prior art does not teach or suggest a method wherein a cleaving oligonucleotide is included in an amplification reaction wherein the cleaving oligonucleotide comprises a sequence complementary to a region overlapping with and adjacent to said target sequence, and further wherein the primers and cleaving oligonucleotide each contain at least 10 bases of the sequence combinations listed in

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parts (1), (2) and (3) of claim 9. The closest prior art, of record, does not teach or suggest the inclusion of such an oligonucleotide in the reaction mixture.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C Switzer whose telephone number is (571) 272-0753. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached by calling (571) 272-0745.

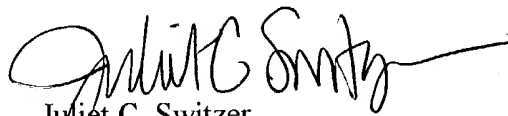
The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-0507.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of

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the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



Juliet C. Switzer
Primary Examiner
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December 22, 2004